

### **REMARKS**

Applicants respectfully request entry of the above amendments and reconsideration of the following arguments pursuant to 37 C.F.R. § 1.111.

#### **1. Status of the Claims**

The status of the claims following entry of the amendment is as follows:

<b>Claims pending:</b>	28-33 and 51-52
<b>Claims rejected:</b>	28-33 and 51-52
<b>Claims canceled:</b>	1-27 and 34-50
<b>Claims amended:</b>	28-30 and 33

#### **2. Support for the Amendments**

Applicants amend claims 28-30 and 33 to more precisely recite the claimed subject matter. Support for the claim amendments can be found at least (1) from the previously presented claims; and (2) at ¶¶ [0021]-[0022] and [0037]-[0042] of the Specification. Applicants do not believe that the amendments add prohibited subject matter that is unsupported by the Specification as filed.

The claims have been amended without prejudice to, or disclaimer of, the canceled subject matter. Applicants reserve the right to file a continuation or divisional application on any subject matter canceled by way of amendments.

#### **3. Restriction Requirement**

The Office makes the prior Restriction / Election Requirement final. Claims 20-27 and 34-50 are withdrawn from further consideration as allegedly drawn to non-elected inventions. Office Action, pages 2-3.

#### **4. Information Disclosure Statements**

Applicants appreciate the Office's acknowledgement of the Information Disclosure Statements (IDSs) filed October 3, 2007; May 6, 2008; July 9, 2008; August 25, 2008; and August 23, 2010.

5. **Acceptance of the Drawings**

Applicants appreciate the Office's acknowledgement that the drawings submitted August 16, 2006, are accepted.

6. **Priority**

Applicants appreciate the Office's acknowledgement that all copies of the certified priority documents have been received.

7. **Rejection Under 35 U.S.C. § 102(b)**

The Office rejects claims 28-29 and 51 under 35 U.S.C. § 102(b) as allegedly anticipated by Suehiro et al., JP 06-009607 ("Suehiro"). Office Action, page 3. Suehiro allegedly discloses the following:

- (1) extracting water-soluble components from tea leaves followed by adsorption on a synthetic adsorbent packed in a chromatography column;
- (2) washing the chromatography column with water and hot water sequentially to remove water-soluble impurities, wherein the hot water is 60 to 90°C;
- (3) eluting catechin oxidative polymerization products in the washing process; washing the adsorbent with water in a ratio of 4:1; and
- (4) extracting tea with hot water at 80°C or higher.

*Id.*, at 3-4. Furthermore, both the selective removal of non-polymerized catechins and the elevated ratio of polymerized catechins to the non-polymerized catechins, as recited in the present claims, are allegedly the results of claimed steps. *Id.* at 4. The Office asserts that it is not necessary for the prior art to recognize these properties. *Id.*

Applicants traverse the rejection to the extent it may be applied to the amended claims. For prior art to anticipate a claim, the reference must disclose each and every element of the claim explicitly or inherently. *See, e.g., In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993). To establish inherency, the Office must prove that the missing descriptive

matter is *necessarily* present in the reference; mere probabilities or possibilities are not sufficient. *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999).

As amended, claim 28 recites *inter alia* (1) “contacting the aqueous liquid with an activated charcoal” (2) “at a temperature of at least 50°C to selectively remove the non-polymerized catechins.” Amended claim 29 recites similar elements (“passing the aqueous extract of tea leaves through the column filled with the activated charcoal ... at a temperature of at least 50°C”). Suehiro fails to disclose at least the above-identified elements. At best, Suehiro may disclose contacting a tea extract with a *gel-type synthetic adsorbent*—“an adsorption process for adsorbing tea catechin components to a chromatography column packed with a gel-type synthetic adsorbent.” *See, e.g.,* Surhiro, *Constitution*, at page 1 and ¶ [0035] (“the aforementioned gel adsorbent can have the main component of a vinyl polymer”). Suehiro does not disclose using an activated charcoal. Suehiro’s synthetic adsorbent is *not* an activated charcoal. Accordingly, Suehiro fails to disclose at least contacting the aqueous liquid with an activated charcoal.

Additionally, both amended claims 28-29 recite contacting the aqueous liquid (*e.g.*, a tea extract) with an activated charcoal at a temperature of 50°C or higher. *See, e.g.*, Examples 2 and 3 of the Specification.<sup>1</sup> Suehiro does not disclose that the aqueous liquid / extract is brought into contact with the adsorbent at a temperature of at least 50°C. The Office is respectfully directed to ¶ [0093] of Suehiro:

[0093]

Next, the second aspect of the invention will be described. The invention is a method of manufacturing tea catechins, briefly, by injecting a tea extract liquid extracted with hot water into a chromatography column packed with a synthetic adsorbent, *washing the chromatography column with only water first and then removing caffeine with hot water of 60 to 95°C*, and eluting out the components remaining in the chromatography column with an aqueous solution containing 50 to 100 vol% of one of methanol, ethanol, and acetone solvents or a mixture thereof.

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<sup>1</sup> “For this operation, the temperature of the liquid extract and the column was set at ...” *See* ¶ [0037] of the Specification. “With its temperature held at 60-65°C, the liquid extract was passed through a column of 400kg particulate activated charcoal (GW-H32/60 of KURARAY CO., LTD.) so that non-polymerized catechins and caffeine were selectively removed.” *See* ¶ [0041] of the Specification.

(emphasis added). The above-emphasized clause indicates that water of a lower temperature is used to wash the column in which both non-polymerized catechins and caffeine remain adsorbed—hot water of 60 to 95°C was applied only subsequently to selectively elute caffeine. A skilled artisan given the above description would have understood that the contacting of the tea extract with the synthetic adsorbent in Suehiro is *not necessarily* kept at the claimed temperature.

Applicants further submit that the present claims are directed to a method of producing a composition rich in polymerized catechins by *having both non-polymerized catechins and caffeine* selectively adsorbed (and ultimately removed). *See, e.g.*, Specification, ¶ [0041].<sup>2</sup> In contrast, Suehiro is directed to a method of collecting non-polymerized catechins by *having only non-polymerized catechins selectively adsorbed*—caffeine is selectively and separately removed. *See supra* Suehiro, ¶ [0093]. Because of the difference as to the adsorbed compounds, the temperature for the contacting step in Suehiro likely differs from the presently claimed temperature.

Given at least these arguments, Suehiro fails to disclose, explicitly or inherently, at least contacting the aqueous liquid or extract with an activated charcoal at a temperature of at least 50°C. As Suehiro fails to disclose each and every claim element, claims 28 and 29 are novel. Dependent claim 51 is likewise novel for at least the same reasons. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

#### 8. **Rejection Under 35 U.S.C. § 103(a)**

The Office rejects claims 28-33 and 52 under 35 U.S.C. § 103(a) as allegedly unpatentable over Seto et al., JP 08-109178 (“Seto”) in view of Yoshiba et al., JP 04-182479 (“Yoshiba”). Office Action, page 5. Seto allegedly teaches the following:

- (1) dissolving 10 grams of green tea extract in 20 mL water and applying it to a glass column packed with 300 mL of a synthetic adsorbent SP-207;
- (2) eluting the column with 1500 mL of a buffer solution at pH 10; and
- (3) concentrating and dry the fraction.

<sup>2</sup> “...so that non-polymerized catechins and caffeine were selectively removed.”

*Id.*, at 5-6. The Office admits that Seto does not “expressly disclose the temperature of the aqueous liquid as 50°C.” *Id.*, at 6. The Office relies upon Yoshiba to cure the defect. Yoshiba allegedly teaches mixing the tea leaves with water at a temperature of 80°C or higher. *Id.* The Office asserts that a skilled artisan at the time would have been motivated to combine Seto and Yoshiba to practice the claimed methods. *Id.*, at 7-8.

Applicants traverse the rejection to the extent it may be applied to the amended claims. “[O]bviousness requires a suggestion of *all* limitations in a claim.” *CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1342, 68 U.S.P.Q.2d 1940, 1947 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985, 180 U.S.P.Q. 580, 583 (C.C.P.A. 1974) (emphasis added). To establish *prima facie* obviousness using a combination of multiple references, the Office must show that the combination or modification must have had expected and predictable results. *See* M.P.E.P. § 2143.

As amended, claim 28 recites *inter alia* (1) “contacting the aqueous liquid with an activated charcoal” (2) “at a temperature of at least 50°C to selectively remove the non-polymerized catechins.” Amended claims 29-30 recite similar elements (claim 29: “passing the aqueous extract of tea leaves through the column filled with the activated charcoal ... at a temperature of at least 50°C”; and claim 30: “contacting the aqueous liquid with an activated charcoal at a temperature of at least 50°C”). The amended claims are nonobvious over cited references for at least the following reasons. First, the combined references fail to teach using an activated charcoal. Seto at best may teach using a synthetic adsorbent. *See, e.g.*, Seto, Constitution, page 1 (“...contact with a synthetic adsorbent...”) and ¶ [0010] (listing various synthetic adsorbents). Seto’s synthetic adsorbent is *not* an activated charcoal. Yoshiba at best may teach using a synthetic adsorbent, but not an activated charcoal. *See, e.g.*, Yoshiba, paragraph bridging pages 6-7 (“adsorbing the extract components to a chromatography column packed with a synthetic adsorbent...”). Yoshiba thus fails to cure Seto’s defects. Seto and Yoshiba, alone or in combination, fail to teach at least using an activated charcoal during the contacting step. Without all claim elements taught, there can be no expectation that the presently claimed methods would have worked predictably.

Additionally, amended claims 28-30 also recite contacting the aqueous liquid (*e.g.*, a tea extract) with the activated charcoal at a temperature of 50°C or higher. *See, e.g.*, Examples 2 and

3 of the Specification.<sup>1</sup> Seto is silent as to the temperature at which the tea extract is brought into contact with an adsorbent.<sup>3</sup> As admitted by the Office, Seto does not “expressly disclose the temperature of the aqueous liquid as 50°C.” Accordingly, Seto does not teach that the contacting between tea extract and the synthetic adsorbent occurs at 50°C or higher. Yoshiba does not cure Seto’s defects. Yoshiba is silent as to the temperature at which the tea extract is injected into a chromatography column packed with an adsorbent.<sup>4</sup> Yet, Yoshiba is relied upon for purportedly teaching that tea leaves are extracted with hot water at a temperature of 80°C or higher. Applicants note that this is the extraction temperature, not the temperature at which the tea extract is brought into contact with the adsorbent. Accordingly, Seta and Yoshiba, alone or in combination, fail to teach at least the recited temperature range. Without all claim elements taught, there can be no expectation that the presently claimed methods would have worked predictably.

The inventors newly discovered that the presently claimed methods selectively remove non-polymerized catechins. See ¶ [0008] of the Specification.<sup>5</sup> Applicants note that obviousness cannot be proven merely by showing that a parameter in a method or process, for example, temperature, could have been modified by routine experimentation. The Office must provide evidence or a rationale of why a skilled artisan would have had some apparent reason to modify the process in a way that would result in the claimed process. See e.g. *Ex parte Whalen*, 89 U.S.P.Q.2d 1078, 1084 (Bd. Pat. App. & Int. 2008) (precedential). In the present application, there is no evidence on the record that a skilled artisan would have had some apparent reason to (1) substitute the synthetic adsorbent with an activated charcoal; and/or (2) adjust the

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<sup>3</sup> “The product obtained by treatment with a resin or an adsorbent is a product obtained by bringing the aforementioned hot-water extract or the organic-solvent extract into contact with a synthetic adsorbent, activated carbon, or the like for collecting tea polyphenol by attaching and detaching or removing components other than tea polyphenol by adsorbing.” See Seto, ¶ [0009].

<sup>4</sup> “These water-soluble components or tea extract liquid is concentrated and then injected into a chromatography column packed with an adsorbent for adsorbing various components to this adsorbent (adsorption process).” See Yoshiba, 2<sup>nd</sup> paragraph on page 8.

<sup>5</sup> “[0008] It has been known that a variety of ingredients in tea can be separated by various resins. For instance, it has been known that detanning and decaffeination are possible by treating with activated charcoal. However, *there has not been known any effective method that can selectively separate polymerized catechins from non-polymerized catechins by means of an adsorbent such as activated charcoal or an adsorbing resin.*” (emphasis added)

temperature upon which the tea extract is brought into contact with the adsorbent, let alone that such modification(s) would have worked.

Furthermore, the presently claimed methods offer unexpected advantages by selectively removing non-polymerized catechins. *See, e.g.*, Abstract and Example 2 of the Specification. Seto may teach a method of manufacturing low-caffeine tea polyphenol by bringing a tea extract into contact with a synthetic adsorbent under an alkaline condition to adsorb and remove caffeine.” *See* Seto, Abstract. Yoshiba may teach “a method that can manufacture tea catechins of high purity at a low cost using tea leaves as a raw material.” *See* Yoshiba, 1<sup>st</sup> full paragraph on page 3. But, neither reference teaches, suggests, or provides motivation to separate polymerized catechins from non-polymerized catechins.

Applicants further submit that Suehiro teaches away from the presently claimed methods. The present claims are directed to a method of producing a composition rich of polymerized catechins by *having both non-polymerized catechins and caffeine* selectively adsorbed (and ultimately removed). In contrast, Suehiro is directed to a method of collecting non-polymerized catechins by *having only non-polymerized catechins selectively adsorbed* —caffeine is selectively and separately removed. *See id.* Example 5 of Suehiro describes obtaining a “manufactured crude tea catechins” composition having 5 wt% caffeine after washing the column with 1.5 L distilled water and 3.5 L of hot water (90°C). *See* Suehiro, ¶¶ [0195]-[0196]. Comparative Example 3 of Suehiro describes obtaining a “manufactured crude tea catechins” composition having 18 wt% of caffeine after washing the column with 4.5 L of hot water (40°C). *See id.*, ¶ [0202]. These results suggest that caffeine is more likely to be eluted at a higher temperature. Since caffeine, together with non-polymerized catechins, is intended to be absorbed on the column in the presently claimed methods, a skilled artisan given the teaching of Suehiro would have avoided a high temperature during the contacting step. The Office is respectfully requested to reconsider in view of the teaching away by Suehiro.

Given at least these arguments, amended claims 28-30 are nonobvious over cited references. Dependent claims 31-33 and 51-52 are likewise nonobvious for at least the same reasons. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

### CONCLUSION

In view of the above arguments and amendments to the claims, Applicants submit that the claims are in condition for allowance and respectfully request reconsideration and timely allowance of the claims.

Should the Office have any questions or comments regarding Applicants' amendments or response, please contact Applicants' undersigned representative at (202) 230-5119. Furthermore, please direct all correspondence to the below-listed address.

In the event that the Office believes that there are fees outstanding in the above-referenced matter and for purposes of maintaining pendency of the application, the Office is authorized to charge the outstanding fees to Deposit Account No. 50-0573. The Office is likewise authorized to credit any overpayment to the same Deposit Account Number.

Respectfully Submitted,

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